UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	
v.	)	**Criminal No. 05-10102-JLT**
JOHN BRUENS, MARY STEWART, MARC SIROCKMAN, MELISSA VAUGHN	)	
Defendants.	)	

GOVERNMENT'S OPPOSITION TO THE DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE TESTIMONY BY SAUL N. MALOZOWSKI, M.D., Ph.D.

Now comes the United States of America, by its attorney, Michael J. Sullivan, United States Attorney for the District of Massachusetts, and opposes the Defendants' Motion *In Limine* to Exclude Testimony By Saul N. Malozowski, M.D., Ph.D. This motion should be denied for the following reasons:

1. Dr. Malozowski's Testimony is Admissible under Fed. R. Evid. 702 and Necessary for the Jury's Understanding of this case.

Dr. Saul N. Malozowski is an Endocrinologist who was employed by the U.S. Food & Drug Administration ("FDA"). Dr. Malozowski was one of the reviewers of the New Drug Application submitted by Serono Laboratories, Inc. ("Serono"). The testimony of Dr. Malozowski at trial will be very limited; his direct examination should take approximately 30 minutes[1].

[1] Although his Grand Jury testimony was broad and covered the regulatory process at the FDA, including clinical trials, these areas are not going to be discussed in Dr. Malozowski's testimony at trial.

At the outset we note that this motion is untimely.[2] The defense asserts that this testimony should be excluded because the allegations in this case "have nothing whatsoever to do with science or regulatory approval of Serostim, the efficacy of competing drugs and other AIDS treatments, or the scientific and medical aspects of the AIDS virus." The defendant's representation that this is the subject of the testimony that the Government will elicit from Dr. Malozowski is not correct.[3]

Dr. Malozowski's testimony will be very directed. After he is qualified,[4] he will be asked to testify about Serostim, the indication for which the FDA approved the drug – AIDS wasting, and, about the incidence and prevalence of AIDS wasting and the factors affecting the incidence and prevalence – from the time the drug was approved in 1996 to until 1999, the date when the

---

[2] The defense states that it filed this motion on April 9, 2007 because of the Exhibit List that was produced by the Government on April 6, 2007. However, in the body of the motion they quote from a Pre-trial Conference on December 18, 2006 in which the Government announced its intention to call Dr. Malozowski of the U.S. Food & Drug Administration as an expert witness in this case. Thus, the defense was on notice in December, 2006 of the Government's intention to call this witness and failed to file this Motion in Limine on March 22, 2007 as called for in the Court's Order of January 16, 2007. This motion is untimely and should be denied.

[3] Had counsel complied with L. R. 7.1, they would have been informed of the substance of the testimony by Dr. Malozowski to be elicited at trial. As it is, they quote statements made by the government at a prior hearing on a Motion to Strike Surplusage – and not a representation of the testimony of Dr. Malozowski. (Transcript of Pretrial Conference on Dec. 18, 2006 at pp. 9-12).

[4] The Defendants could stipulate to his qualifications.

Government alleges this conspiracy began. That is the sum and substance of his testimony. It is intended to aid the jury to understand the facts underlying this drug and which led, in part, to the situation that confronted the defendants' marketing of this drug. This is entirely permissible under Fed. R. Evid. 702 and will certainly not cause reversible error. This testimony is relevant, but does not go to the ultimate issue in the case.

Although this case isn't about the "science" of Serostim, it is not completely divorced from the science relating to Serostim. Serostim is not a commonly known drug, such as, for example, an antihistamine or cardiac drug with which jurors may be familiar. This drug was approved by the FDA to treat a very specific condition in HIV and AIDS, AIDS wasting. Most jurors will likely have never heard of the drug or the condition for which it was approved. A description of the indication for which Serostim was approved is certainly scientific, as is an explanation of the condition, AIDS wasting. The government must explain to the jurors these scientific facts about the drug that is the subject of this case.

The motivation that fueled the need to offer the kickbacks that the government alleges the defendants offered to physicians is that this drug was very hard to sell. Some of the reasons that the drug was difficult to sell include some of these scientific facts, its method of administration and other factors. These scientific facts are not ones that are necessarily in the

ken of the jury. This expert testimony is necessary to assist the jury in understanding the evidence.

The defendants assert that there are other witnesses that can address these issues. While we expect other witnesses to address the challenges that they faced in the marketplace selling the drug (including their understanding of the impact of other drugs that entered the marketplace at or around the same time as Serostim), they will speak to their own understanding of the drug, AIDS wasting and other factors. These witnesses are not qualified or appropriate witnesses to testify as to the FDA's views about this drug. The Government is entitled to present to the jury the FDA's perspective on these issues.

2. Conclusion:

Accordingly, for all the foregoing reasons, the Court should deny the Defendants' Motion *In Limine* to Exclude Testimony By Saul N. Malozowski, M.D., Ph.D. and permit this limited testimony.

Respectfully submitted,

MICHAEL J. SULLIVAN
United States Attorney

By: /s/ Mary Elizabeth Carmody

Mary Elizabeth Carmody
Susan M. Poswistilo
Assistant U.S. Attorneys
U. S. Attorney's Office
John Joseph Moakley U.S. Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3290

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Mary Elizabeth Carmody
_____
Mary Elizabeth Carmody
Assistant United States Attorney

Date: April 12, 2007